

What is claimed is:

1. A polynucleotide vaccine composition comprising a nucleic acid sequence that encodes a *Bacillus anthracis* antigen, wherein said nucleic acid sequence is operatively linked to a promoter suitable for expression of the antigen in a mammalian cell.

2. The composition of claim 1 wherein the nucleic acid sequence is present in a plasmid vector.

3. The composition of claim 1 wherein the nucleic acid sequence encodes an antigen obtained or derived from the Protective Antigen of *Bacillus anthracis*.

4. The composition of claim 3 wherein the antigen encoded by the nucleic acid sequence is substantially homologous to the full-length Protective Antigen protein.

5. A polynucleotide vaccine composition, said composition comprising: a first nucleic acid sequence that encodes a *Bacillus anthracis* antigen; and a second nucleic acid sequence that encodes a leader signal peptide operatively linked to the first nucleic acid sequence, wherein said first and said second nucleic acid sequences are operatively linked to a promoter suitable for expression thereof in a mammalian cell and said leader signal peptide provides for the secretion of the encoded antigen.

6. The composition of claim 1 further comprising an adjuvant component.

7. The composition of claim 6 wherein said adjuvant component is present in the composition in the form of a nucleic acid sequence.

8. The composition of claim 7 wherein said adjuvant component is a CpG sequence.

9. The composition of claim 7 wherein said adjuvant component is a further nucleic acid sequence that encodes a polypeptide adjuvant.

10. The composition of claim 6 wherein said adjuvant component is present in the composition in a form other than a nucleic acid sequence.

11. The composition of claim 10 wherein said adjuvant component is selected from the group consisting of a polypeptide, a lipid, a non-protein hormone, and a vitamin.

12. The composition of claim 11 wherein the adjuvant component comprises monophosphoryl lipid A.

13. The composition of claim 11 wherein the adjuvant component comprises a saponin or a derivative thereof.

14. The composition of claim 13 wherein the adjuvant component comprises Quil-A.

15. The composition of claim 1 further comprising a pharmaceutically acceptable excipient or vehicle.

16. The composition of claim 1 wherein said composition is in particulate form.

17. The composition of claim 16 wherein the nucleic acid sequence is coated onto a core carrier particle.

18. The composition of claim 17 wherein the core carrier particle has an average diameter of about 0.1 to about 10 $\mu$ m.

19. The composition of claim 17 wherein the core carrier particle comprises a metal.

20. The composition of claim 19 wherein the metal is gold.

21. The composition of claim 1 further comprising a transfection facilitating agent.

22. The composition of claim 5 further comprising an adjuvant component.

23. The composition of claim 22 wherein said adjuvant component is present in the composition in the form of a nucleic acid sequence.

24. The composition of claim 23 wherein said adjuvant component is a CpG sequence.

25. The composition of claim 23 wherein said adjuvant component is a further nucleic acid sequence that encodes a polypeptide adjuvant.

26. The composition of claim 5 wherein said adjuvant component is present in the composition in a form other than a nucleic acid sequence.

27. The composition of claim 26 wherein said adjuvant component is selected from the group consisting of a polypeptide, a lipid, a non-protein hormone, and a vitamin.

5           28. The composition of claim 27 wherein the adjuvant component comprises monophosphoryl lipid A.

29. The composition of claim 27 wherein the adjuvant component comprises a saponin or a derivative thereof.

10           30. The composition of claim 29 wherein the adjuvant component comprises Quil-A.

31. The composition of claim 5 further comprising a pharmaceutically acceptable excipient or vehicle.

15           32. The composition of claim 5 wherein said composition is in particulate form.

20           33. The composition of claim 32 wherein the nucleic acid sequence is coated onto a core carrier particle.

34. The composition of claim 33 wherein the core carrier particle has an average diameter of about 0.1 to about 10 $\mu$ m.

25           35. The composition of claim 34 wherein the core carrier particle comprises a metal.

36. The composition of claim 35 wherein the metal is gold.

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37. The composition of claim 5 further comprising a transfection facilitating agent.

5 38. A method for eliciting an immune response against *Bacillus anthracis* in a subject, the method comprising administering the vaccine composition of claim 5 to the subject, whereby upon introduction to the subject, the nucleic acid sequence is expressed to provide the *Bacillus anthracis* antigen in an amount sufficient to elicit said immune response.

10 39. The method of claim 38 wherein the vaccine composition is administered directly into skin or muscle tissue.

40. The method of claim 38 wherein the vaccine composition is administered to the subject in particulate form.

15 41. The method of claim 38 wherein the nucleic acid sequence is coated onto a core carrier particle and administered to the subject using a particle-mediated delivery technique.

20 42. The method of claim 38 wherein the vaccine composition further comprises an adjuvant component.

43. The method of claim 38 further comprising the step of administering a second vaccine composition to the subject.

25 44. The method of claim 43 wherein the second vaccine composition is an anti-*Bacillus anthracis* vaccine containing the peptide form of the Protective Antigen from *Bacillus anthracis*.

45. The method of claim 43 wherein the second vaccine composition is administered to the subject in a boosting step.

5 46. The method of claim 43 wherein both vaccine compositions are administered to the same site in the subject.

47. The method of claim 43 wherein the vaccine compositions are administered concurrently.

10 48. The method of claim 43 wherein the vaccine compositions are combined to provide a single composition.

49. A method for using a *Bacillus anthracis* antigen to induce a protective immune response in a subject, said method comprising:

15 (a) providing an expression cassette containing a nucleic acid sequence encoding the Protective Antigen from *Bacillus anthracis* operatively linked to control sequences that direct expression of the Protective Antigen when introduced into tissue of the subject; and

20 (b) administering the expression cassette to tissue of the subject such that the Protective Antigen is expressed in an amount sufficient to induce said protective immune response in the subject.

50. The method of claim 49 wherein the expression cassette is present in a plasmid vector.

25 51. A method for using a *Bacillus anthracis* antigen to induce an immune response in a subject, said method comprising:

30 (a) providing an expression cassette containing a first nucleic acid sequence encoding the Protective Antigen from *Bacillus anthracis* and a second nucleic acid sequence that encodes a leader signal peptide, wherein said first and

second nucleic acid sequences are operatively linked to each other and to control sequences that direct expression of said sequences when introduced into tissue of the subject and said leader signal peptide provides for the secretion of the encoded Protective Antigen; and

- 5           (b)     administering the expression cassette to tissue of the subject such that the Protective Antigen is expressed in an amount sufficient to induce said immune response in the subject.

10           52.     The method of claim 51 wherein the leader signal peptide is the tissue plasminogen activator (TPA) leader signal peptide.

          53.     The method of claim 51 wherein the expression cassette is present in a plasmid vector.

15           54.     The method of claim 53 wherein the plasmid vector is administered directly into skin or muscle tissue of the subject.

          55.     The method of claim 53 wherein the plasmid vector is administered to the subject in particulate form.

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          56.     The method of claim 55 wherein the plasmid vector is coated onto a core carrier particle and administered to the subject using a particle-mediated delivery technique.